

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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KICIA GRACE,	:
	:
Plaintiff,	: Civil Action No.: 1:07-cv-4081
	:
-against-	:
JOHNSON & JOHNSON, ORTHO-McNEIL	: DEFENDANTS JOHNSON & JOHNSON,
PHARMACEUTICAL, INC., JOHNSON &	: ORTHO-McNEIL PHARMACEUTICAL,
JOHNSON PHARMACEUTICAL	: INC. and JOHNSON & JOHNSON
RESEARCH & DEVELOPMENT, L.L.C.,	: PHARMACEUTICAL RESEARCH AND
DESIREE A. CLARKE, M.D., and WEST	: DEVELOPMENT, LLC'S VERIFIED
CARE MEDICAL ASSOCIATES,	: ANSWER, AFFIRMATIVE DEFENSES
	: AND JURY DEMAND
	:
Defendants.	:
-----	X

Defendants Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil"), Johnson & Johnson ("J&J"), and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. ("J&JPRD"), (collectively referred to herein as "Defendants"), by and through their undersigned counsel, hereby respond to the Complaint (the "Complaint") filed by Plaintiff Kicia Grace (referred to herein as "Plaintiff") as follows:

NATURE OF THE CASE

1. In response to Paragraph 1 of the Complaint, Defendants admit that Plaintiff purports to bring an action. Defendants otherwise deny the allegations contained in Paragraph 1 of the Complaint.

2. In response to Paragraph 2 of the Complaint, Defendants admit that Ortho-McNeil and/or J&JPRD designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the contraceptive product known as Ortho Evra®. Defendants deny all remaining allegations contained in Paragraph 2 of the Complaint.

3. To the extent that Paragraph 3 of the Complaint refers to a package insert, Defendants state that the package insert speaks for itself and refer to that package insert for a fair and accurate portrayal of its contents. Defendants otherwise deny the remaining allegations contained in Paragraph 3 of the Complaint.

4. Defendants deny the allegations contained in Paragraph 4 of the Complaint.

5. Defendants deny the allegations contained in Paragraph 5 of the Complaint.

6. To the extent that Paragraph 6 of the Complaint refers to a package insert, Defendants state that the package insert speaks for itself and refer to that package insert for a fair and accurate portrayal of its contents. Defendants otherwise deny the remaining allegations contained in Paragraph 6 of the Complaint.

7. Defendants deny the allegations contained in Paragraph 7 of the Complaint.

8. To the extent that Paragraph 8 of the Complaint refers to a package insert, Defendants state that the package insert speaks for itself and refer to that package insert for a fair and accurate portrayal of its contents. Defendants otherwise deny the remaining allegations contained in Paragraph 8 of the Complaint.

9. Responding to Paragraph 9 of the Complaint, Defendants admit that on or about November 10, 2005, FDA approved updated labeling for the contraceptive product known as Ortho Evra®. To the extent that Paragraph 9 refers to a package insert, Defendants state that the

package insert speaks for itself and refer to that package insert for a fair and accurate portrayal of its contents. Defendants otherwise deny the remaining allegations contained in Paragraph 9 of the Complaint.

10. To the extent that Paragraph 10 of the Complaint refers to a package insert, Defendants state that the package insert speaks for itself and refer to that package insert for a fair and accurate portrayal of its contents. Defendants otherwise deny the remaining allegations contained in Paragraph 10 of the Complaint.

11. Defendants deny that the contraceptive product known as Ortho Evra® is “defective” and therefore deny the allegations contained in Paragraph 11 of the Complaint.

12. Defendants deny the allegations contained in Paragraph 12 of the Complaint.

13. Defendants admit that Plaintiff seeks compensatory damages in Paragraph 13 of the Complaint. Defendants deny that Plaintiff is entitled to any damages whatsoever and otherwise deny the allegations contained in Paragraph 13 of the Complaint.

PARTY PLAINTIFF

14. Defendants are without sufficient knowledge to form a belief as to the truth of the allegations contained in Paragraph 14 of the Complaint.

15. Defendants are without sufficient knowledge to form a belief as to the truth of the allegations contained in Paragraph 15 of the Complaint.

16. The allegations in Paragraph 16 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 16 of the Complaint.

17. The allegations in Paragraph 17 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 17 of the Complaint.

18. Defendants are without sufficient knowledge to form a belief as to the truth of the allegations contained in Paragraph 18 of the Complaint.

19. Defendants are without sufficient knowledge to form a belief as to the truth of the allegations contained in Paragraph 19 of the Complaint and otherwise deny the same.

20. Defendants deny the allegations contained in Paragraph 20 of the Complaint.

PARTY DEFENDANTS

21. The allegations in Paragraph 21 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 21 of the Complaint.

22. The allegations in Paragraph 22 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 22 of the Complaint.

23. The allegations in Paragraph 23 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 23 of the Complaint.

24. The allegations in Paragraph 24 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 24 of the Complaint.

25. The allegations in Paragraph 25 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 25 of the Complaint.

26. The allegations in Paragraph 26 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 26 of the Complaint.

27. The allegations in Paragraph 27 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 27 of the Complaint.

28. The allegations in Paragraph 28 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 28 of the Complaint.

29. The allegations in Paragraph 29 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are

without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 29 of the Complaint.

30. The allegations in Paragraph 30 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 30 of the Complaint.

31. The allegations in Paragraph 31 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 31 of the Complaint.

32. The allegations in Paragraph 32 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 32 of the Complaint.

33. The allegations in Paragraph 33 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 33 of the Complaint.

34. The allegations in Paragraph 34 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 34 of the Complaint.

35. The allegations in Paragraph 35 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 35 of the Complaint.

36. The allegations in Paragraph 36 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 36 of the Complaint.

37. The allegations in Paragraph 37 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 37 of the Complaint.

38. Defendants admit the allegations contained in Paragraph 38 of the Complaint.

39. Defendants admit the allegations contained in Paragraph 39 of the Complaint.

40. Defendants are without sufficient knowledge to form a belief as to the truth of the allegations contained in Paragraph 40 of the Complaint and otherwise deny the same.

41. Defendants are without sufficient knowledge to form a belief as to the truth of the allegations contained in Paragraph 41 of the Complaint and otherwise deny the same.

42. In response to Paragraph 42 of the Complaint, Defendants admit that Ortho-McNeil and/or J&JPRD designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the contraceptive product known as Ortho Evra®. Defendants otherwise deny the allegations contained in Paragraph 42 of the Complaint.

43. Defendants admit the allegations contained in Paragraph 43 of the Complaint.

44. Defendants admit the allegations contained in Paragraph 44 of the Complaint.

45. In response to Paragraph 45 of the Complaint, Defendants state that J&J is a holding company that does not manufacture or sell any products in the State of New York. Defendants therefore deny the allegations contained in Paragraph 45 of the Complaint.

46. In response to Paragraph 46 of the Complaint, Defendants state that J&J is a holding company that does not manufacture or sell any products in the State of New York. Defendants therefore deny the allegations contained in Paragraph 46 of the Complaint.

47. In response to Paragraph 47 of the Complaint, Defendants state that J&J is a holding company that does not manufacture or sell any products in the State of New York. Defendants therefore deny the allegations contained in Paragraph 47 of the Complaint.

48. Defendants admit the allegations contained in Paragraph 48 of the Complaint.

49. Defendants admit the allegations contained in Paragraph 49 of the Complaint.

50. In response to Paragraph 50 of the Complaint, Defendants state that J&JPRD performs research and development work for the pharmaceutical business units of J&J and does not manufacture or sell any products in the State of New York. Defendants therefore deny the allegations contained in Paragraph 50 of the Complaint.

51. In response to Paragraph 51 of the Complaint, Defendants state that J&JPRD performs research and development work for the pharmaceutical business units of J&J and does not manufacture or sell any products in the State of New York. Defendants therefore deny the allegations contained in Paragraph 51 of the Complaint.

52. In response to Paragraph 52 of the Complaint, Defendants state that J&JPRD performs research and development work for the pharmaceutical business units of J&J and does not manufacture or sell any products in the State of New York. Defendants therefore deny the allegations contained in Paragraph 52 of the Complaint.

FACTUAL BACKGROUND

53. In response to Paragraph 53 of the Complaint, Defendants admit that Ortho-McNeil and/or J&JPRD designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the contraceptive product known as Ortho Evra®. Defendants deny all remaining allegations contained in Paragraph 53 of the Complaint.

54. Defendants admit the allegations contained in Paragraph 54 of the Complaint.

55. Defendants admit the allegations contained in Paragraph 55 of the Complaint.

56. Defendants admit the allegations contained in Paragraph 56 of the Complaint.

57. In response to Paragraph 57 of the Complaint, Defendants admit that Ortho-McNeil has been involved in research and development of forms of contraception since 1931 and hormone combination contraception as early as 1957. Defendants otherwise deny the allegations contained in Paragraph 57 of the Complaint.

58. Defendants admit the allegations contained in Paragraph 58 of the Complaint.

59. Defendants admit the allegations contained in Paragraph 59 of the Complaint.

60. The allegations contained in Paragraph 60 of the Complaint are immaterial to the claims set forth in the Complaint and are therefore improper under Federal Rules of Civil Procedure 11 and 12. Accordingly, no response is required to Paragraph 60.

61. The allegations contained in Paragraph 61 of the Complaint are immaterial to the claims set forth in the Complaint and are therefore improper under Federal Rules of Civil Procedure 11 and 12. Accordingly, no response is required to Paragraph 61.

62. The allegations contained in Paragraph 62 of the Complaint are immaterial to the claims set forth in the Complaint and are therefore improper under Federal Rules of Civil Procedure 11 and 12. Accordingly, no response is required to Paragraph 62.

63. The allegations contained in Paragraph 63 of the Complaint are immaterial to the claims set forth in the Complaint and are therefore improper under Federal Rules of Civil Procedure 11 and 12. Accordingly, no response is required to Paragraph 63. To the extent a response is required, Defendants state that the allegation that Ortho-McNeil “is the world’s leading manufacturer or prescription contraceptives” is without context and therefore vague. Defendants therefore are without sufficient knowledge to form a belief as to the truth of the allegations contained in Paragraph 63 of the Complaint.

64. The allegations contained in Paragraph 64 of the Complaint are immaterial to the claims set forth in the Complaint and are therefore improper under Federal Rules of Civil Procedure 11 and 12. Accordingly, no response is required to Paragraph 64. To the extent a response is required, Defendants state that the allegation that Ortho-McNeil “is the current market leader in oral and Patch contraceptive products” is without context and therefore vague. Defendants therefore are without sufficient knowledge to form a belief as to the truth of the allegations contained in Paragraph 64 of the Complaint.

65. In response to Paragraph 65 of the Complaint, Defendants admit that Ortho-McNeil utilized direct-to-consumer advertising to market, promote, and/or advertise the

contraceptive product known as Ortho Evra®. Defendants otherwise deny the allegations contained in Paragraph 65 of the Complaint.

66. In response to Paragraph 66 of the Complaint are immaterial to the claims set forth in the Complaint and are therefore improper under Federal Rules of Civil Procedure 11 and 12. Accordingly, no response is required to Paragraph 66. To the extent a response is required, Defendants state that the allegation that Ortho Evra® “has become one of the most popular forms of birth control and the fastest growing hormonal contraceptive in the United States since 2003” is without context and therefore vague. Defendants therefore are without sufficient knowledge to form a belief as to the truth of the allegations contained in Paragraph 66 of the Complaint.

67. In response to Paragraph 67, Defendants admit that the contraceptive product known as Ortho Evra® received approval from the Food and Drug Administration as a prescription drug on or about November 20, 2001. Defendants otherwise deny the allegations contained in Paragraph 67 of the Complaint.

68. Defendants deny the allegations contained in Paragraph 68 of the Complaint.

69. Defendants deny the allegations contained in Paragraph 69 of the Complaint.

70. To the extent that Paragraph 70 refers to a package insert, Defendants state that the package insert speaks for itself and refer to that package insert for a fair and accurate portrayal of its contents. Defendants otherwise deny the allegations contained in Paragraph 70 of the Complaint.

71. Defendants deny the allegations contained in Paragraph 71 of the Complaint.

72. To the extent that Paragraph 72 of the Complaint refers to documents, Defendants state that those documents speak for themselves, and Defendants refer to those documents for a

fair and accurate portrayal of their contents. Defendants otherwise deny the allegations contained in Paragraph 72 of the Complaint.

73. Defendants deny the allegations contained in Paragraph 73 of the Complaint.

74. Defendants deny the allegations contained in Paragraph 74 of the Complaint.

75. Defendants deny the allegations contained in Paragraph 75 of the Complaint.

76. Defendants deny the allegations contained in Paragraph 76 of the Complaint.

77. Defendants deny the allegations contained in Paragraph 77 of the Complaint.

FIRST CAUSE OF ACTION
(MEDICAL MALPRACTICE)

78. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

79. The allegations in Paragraph 79 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 79 of the Complaint.

80. The allegations in Paragraph 80 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 80 of the Complaint.

81. The allegations in Paragraph 81 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 81 of the Complaint.

82. The allegations in Paragraph 82 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 82 of the Complaint.

83. The allegations in Paragraph 83 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 83 of the Complaint.

84. The allegations in Paragraph 84 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 84 of the Complaint.

85. The allegations in Paragraph 85 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 85 of the Complaint.

86. The allegations in Paragraph 86 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 86 of the Complaint.

87. The allegations in Paragraph 87 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 87 of the Complaint.

88. The allegations in Paragraph 88 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 88 of the Complaint.

89. The allegations in Paragraph 89 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 89 of the Complaint.

SECOND CAUSE OF ACTION
(LACK OF INFORMED CONSENT)

90. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

91. The allegations in Paragraph 91 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 91 of the Complaint.

92. The allegations in Paragraph 92 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 92 of the Complaint.

93. The allegations in Paragraph 93 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 93 of the Complaint.

94. The allegations in Paragraph 94 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 94 of the Complaint.

95. The allegations in Paragraph 95 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 95 of the Complaint.

96. The allegations in Paragraph 96 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 96 of the Complaint.

97. The allegations in Paragraph 97 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 97 of the Complaint.

98. The allegations in Paragraph 98 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 98 of the Complaint.

99. The allegations in Paragraph 99 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 99 of the Complaint.

100. The allegations in Paragraph 100 of the Complaint are directed at other defendants, and therefore no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to other defendants and otherwise deny the allegations contained in Paragraph 100 of the Complaint.

THIRD CAUSE OF ACTION
(NEGLIGENCE)

101. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

102. Defendants deny the allegations contained in Paragraph 102 of the Complaint.

103. Defendants deny the allegations contained in Paragraph 103 of the Complaint.

104. Defendants deny the allegations contained in Paragraph 104 of the Complaint.

105. Defendants deny the allegations contained in Paragraph 105 of the Complaint.

106. Defendants deny the allegations contained in Paragraph 106 of the Complaint.

107. Defendants deny the allegations contained in Paragraph 107 of the Complaint.

108. Defendants deny the allegations contained in Paragraph 108 of the Complaint.

109. Defendants deny the allegations contained in Paragraph 109 of the Complaint.

110. Defendants deny the allegations contained in Paragraph 110 of the Complaint.

111. Defendants deny the allegations contained in Paragraph 111 of the Complaint.

112. Defendants deny the allegations contained in Paragraph 112 of the Complaint.

113. Defendants deny the allegations contained in Paragraph 113 of the Complaint.

FOURTH CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY)

114. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

115. In response to Paragraph 115 of the Complaint, Defendants admit that Ortho-McNeil and/or J&JPRD designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the contraceptive product known as Ortho Evra®. Defendants deny all remaining allegations contained in Paragraph 115 of the Complaint.

116. In response to Paragraph 116, Defendants state that Ortho-McNeil intends for the contraceptive product known as Ortho Evra® to reach consumers without substantial change in the condition in which it was sold. Defendants otherwise are without sufficient knowledge to form a belief as to the truth of the remaining allegations contained in Paragraph 116 of the Complaint.

117. Defendants deny the allegations contained in Paragraph 117 of the Complaint.

118. Defendants deny the allegations contained in Paragraph 118 of the Complaint.

119. Defendants deny the allegations contained in Paragraph 119 of the Complaint.

120. Defendants deny the allegations contained in Paragraph 120 of the Complaint.

121. Defendants deny the allegations contained in Paragraph 121 of the Complaint.

122. Defendants are without sufficient knowledge to form a belief as to the truth of the allegations contained in Paragraph 121 of the Complaint.

123. Defendants deny the allegations contained in Paragraph 123 of the Complaint.

124. Defendants deny the allegations contained in Paragraph 124 of the Complaint.

125. Defendants deny the allegations contained in Paragraph 125 of the Complaint.

126. Defendants deny the allegations contained in Paragraph 126 of the Complaint.

127. Defendants deny the allegations contained in Paragraph 127 of the Complaint.

128. Defendants deny the allegations contained in Paragraph 128 of the Complaint.

129. In response to Paragraph 129, Defendants deny that the contraceptive product known as Ortho Evra® is defective. Defendants otherwise are without sufficient knowledge to form a belief as to the truth of the allegations contained in Paragraph 129 of the Complaint.

130. Defendants deny the allegations contained in Paragraph 130 of the Complaint.

131. Defendants deny the allegations contained in Paragraph 131 of the Complaint.

132. Defendants deny the allegations contained in Paragraph 132 of the Complaint.

133. Defendants deny the allegations contained in Paragraph 133 of the Complaint.

134. Defendants deny the allegations contained in Paragraph 134 of the Complaint.

135. Defendants deny the allegations contained in Paragraph 135 of the Complaint.

136. Defendants deny the allegations contained in Paragraph 136 of the Complaint.

137. Defendants deny the allegations contained in Paragraph 137 of the Complaint.

138. Defendants deny the allegations contained in Paragraph 138 of the Complaint.

FIFTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)

139. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

140. Defendants deny the allegations contained in Paragraph 140 of the Complaint.

141. Defendants deny the allegations contained in Paragraph 141 of the Complaint.

142. Defendants deny the allegations contained in Paragraph 142 of the Complaint.

143. To the extent that Paragraph 143 refers to Plaintiff's state of mind, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 143 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 143 of the Complaint.

144. To the extent that Paragraph 144 refers to the state of mind of physicians and other health care providers, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 144 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 144 of the Complaint.

145. Defendants deny the allegations contained in Paragraph 145 of the Complaint.

146. Defendants deny the allegations contained in Paragraph 146 of the Complaint.

147. Defendants deny the allegations contained in Paragraph 147 of the Complaint.

148. Defendants deny the allegations contained in Paragraph 148 of the Complaint.

149. Defendants deny the allegations contained in Paragraph 149 of the Complaint.

150. Defendants deny the allegations contained in Paragraph 150 of the Complaint.

SIXTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTIES)

151. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

152. In response to Paragraph 152 of the Complaint, Defendants admit that Ortho-McNeil and/or J&JPRD compounded, manufactured, tested, advertised, promoted, marketed,

sold and distributed the contraceptive product known as Ortho Evra®. Defendants deny all remaining allegations contained in Paragraph 152 of the Complaint.

153. In response to Paragraph 153, Defendants admit that Ortho-McNeil marketed the contraceptive product known as Ortho Evra® to physicians and other health care providers as a contraceptive which, when used properly, is intended to prevent pregnancy. Defendants otherwise deny the allegations contained in Paragraph 153 of the Complaint.

154. In response to Paragraph 154 of the Complaint, Defendants admit that Ortho-McNeil marketed the contraceptive product known as Ortho Evra® to physicians and other health care providers as a contraceptive which, when used properly, is intended to prevent pregnancy. Defendants otherwise deny the allegations contained in Paragraph 154 of the Complaint.

155. Defendants deny the allegations contained in Paragraph 155 of the Complaint.

156. To the extent that Paragraph 156 refers to the state of mind of Plaintiff and others, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 156 of the Complaint. Defendants otherwise deny the allegations contained in Paragraph 156 of the Complaint.

157. To the extent that Paragraph 157 refers to the state of mind of Plaintiff and others, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 157 of the Complaint. Defendants otherwise deny the allegations contained in Paragraph 157 of the Complaint.

158. Defendants deny the allegations contained in Paragraph 158 of the Complaint.

159. Defendants deny the allegations contained in Paragraph 159 of the Complaint.

160. Defendants deny the allegations contained in Paragraph 160 of the Complaint.

161. Defendants deny the allegations contained in Paragraph 161 of the Complaint.

162. Defendants deny the allegations contained in Paragraph 162 of the Complaint.

SEVENTH CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

163. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

164. Defendants deny the allegations contained in Paragraph 164 of the Complaint.

165. Defendants deny the allegations contained in Paragraph 165 of the Complaint.

166. Defendants deny the allegations contained in Paragraph 166 of the Complaint.

167. Defendants deny the allegations contained in Paragraph 167 of the Complaint.

168. To the extent that Paragraph 168 refers to the state of mind of Plaintiff, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 168 of the Complaint. Defendant otherwise deny the allegations contained in Paragraph 168 of the Complaint.

169. To the extent that Paragraph 169 refers to the state of mind of Plaintiff, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 169 of the Complaint. Defendants otherwise deny the allegations contained in Paragraph 169 of the Complaint.

170. Defendants deny the allegations contained in Paragraph 170 of the Complaint.

171. Defendants deny the allegations contained in Paragraph 171 of the Complaint.

172. Defendants deny the allegations contained in Paragraph 172 of the Complaint.

173. Defendants deny the allegations contained in Paragraph 173 of the Complaint.

174. Defendants deny the allegations contained in Paragraph 174 of the Complaint.

175. Defendants deny the allegations contained in Paragraph 175 of the Complaint.

EIGHTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)

176. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

177. Defendants deny the allegations contained in Paragraph 177 of the Complaint.

178. Defendants deny the allegations contained in Paragraph 178 of the Complaint.

179. Defendants deny the allegations contained in Paragraph 179 of the Complaint.

180. Defendants deny the allegations contained in Paragraph 180 of the Complaint.

181. Defendants deny the allegations contained in Paragraph 181 of the Complaint.

182. Defendants deny the allegations contained in Paragraph 182 of the Complaint.

183. Defendants deny the allegations contained in Paragraph 183 of the Complaint.

184. Defendants deny the allegations contained in Paragraph 184 of the Complaint.

185. To the extent that Paragraph 185 refers to the state of mind of Plaintiff and others, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 185 of the Complaint. Defendants otherwise deny the allegations contained in Paragraph 185 of the Complaint.

186. Defendants deny the allegations contained in Paragraph 186 of the Complaint.

187. Defendants deny the allegations contained in Paragraph 187 of the Complaint.

188. Defendants deny the allegations contained in Paragraph 188 of the Complaint.

NINTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

189. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

190. Defendants deny the allegations contained in Paragraph 190 of the Complaint.

191. Defendants deny the allegations contained in Paragraph 191 of the Complaint.

192. Defendants deny the allegations contained in Paragraph 192 of the Complaint.

193. Defendants deny the allegations contained in Paragraph 193 of the Complaint.

194. Defendants deny the allegations contained in Paragraph 194 of the Complaint.

195. Defendants deny the allegations contained in Paragraph 195 of the Complaint.

196. Defendants deny the allegations contained in Paragraph 196 of the Complaint.

TENTH CAUSE OF ACTION
(FRAUD AND DECEIT)

197. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.

198. In response to Paragraph 198 of the Complaint, Defendants admit that J&JPRD conducted research on the contraceptive product known as Ortho Evra®. Defendants deny all remaining allegations contained in Paragraph 198 of the Complaint.

199. Defendants deny the allegations contained in Paragraph 199 of the Complaint.

200. Defendants deny the allegations contained in Paragraph 200 of the Complaint.

201. Defendants deny the allegations contained in Paragraph 201 of the Complaint.

202. Defendants deny the allegations contained in Paragraph 202 of the Complaint.

203. To the extent that Paragraph 203 of the Complaint refers to information contained in documents or other media, Defendants state that those documents or other media speak for themselves, and Defendants refer to those documents or other media for a fair and accurate portrayal of their contents. Defendants otherwise deny the allegations contained in Paragraph 203 of the Complaint.

204. To the extent that Paragraph 204 of the Complaint refers to information contained in documents or other media, Defendants state that those documents or other media speak for themselves, and Defendants refer to those documents or other media for a fair and accurate portrayal of their contents. Defendants otherwise deny the allegations contained in Paragraph 204 of the Complaint.

205. To the extent that Paragraph 205 of the Complaint refers to information contained in documents or other media, Defendants state that those documents or other media speak for themselves, and Defendants refer to those documents or other media for a fair and accurate portrayal of their contents. Defendants otherwise deny the allegations contained in Paragraph 205 of the Complaint.

206. To the extent that Paragraph 206 of the Complaint refers to information contained in documents or other media, Defendants state that those documents or other media speak for themselves, and Defendants refer to those documents or other media for a fair and accurate portrayal of their contents. Defendants otherwise deny the allegations contained in Paragraph 206 of the Complaint.

207. To the extent that Paragraph 207 of the Complaint refers to information contained in documents or other media, Defendants state that those documents or other media speak for

themselves, and Defendants refer to those documents or other media for a fair and accurate portrayal of their contents. Defendants otherwise deny the allegations contained in Paragraph 207 of the Complaint.

208. Defendants deny the allegations contained in Paragraph 208 of the Complaint.

209. Defendants deny the allegations contained in Paragraph 209 of the Complaint.

210. Defendants deny the allegations contained in Paragraph 210 of the Complaint.

211. Defendants deny the allegations contained in Paragraph 211 of the Complaint.

212. Defendants deny the allegations contained in Paragraph 212 of the Complaint.

213. Defendants deny the allegations contained in Paragraph 213 of the Complaint.

214. Defendants deny the allegations contained in Paragraph 214 of the Complaint.

215. To the extent that Paragraph 215 of the Complaint refers to information contained in documents or other media, Defendants state that those documents or other media speak for themselves, and Defendants refer to those documents or other media for a fair and accurate portrayal of their contents. Defendants otherwise deny the allegations contained in Paragraph 215 of the Complaint.

216. To the extent that Paragraph 216 of the Complaint refers to information contained in documents or other media, Defendants state that those documents or other media speak for themselves, and Defendants refer to those documents or other media for a fair and accurate portrayal of their contents. Defendants otherwise deny the allegations contained in Paragraph 216 of the Complaint.

217. Defendants deny the allegations contained in Paragraph 217 of the Complaint.

218. Defendants deny the allegations contained in Paragraph 218 of the Complaint.

219. Defendants deny the allegations contained in Paragraph 219 of the Complaint.

220. Defendants deny the allegations contained in Paragraph 220 of the Complaint.

221. Defendants deny the allegations contained in Paragraph 221 of the Complaint.

222. Defendants deny the allegations contained in Paragraph 222 of the Complaint.

223. In response to Paragraph 223 of the Complaint, Defendants admit that Ortho-McNeil utilized direct-to-consumer advertising to market, promote, and/or advertise the contraceptive product known as Ortho Evra®. Defendants otherwise deny the allegations contained in Paragraph 223 of the Complaint.

224. To the extent that Paragraph 224 refers to the state of mind of Plaintiff and others, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 224 of the Complaint. Defendants otherwise deny the allegations contained in Paragraph 224 of the Complaint.

225. To the extent that Paragraph 225 refers to the state of mind of Plaintiff and others, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 225 of the Complaint. Defendants otherwise deny the allegations contained in Paragraph 225 of the Complaint.

226. To the extent that Paragraph 226 refers to the state of mind of Plaintiff and others, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 226 of the Complaint. Defendants otherwise deny the allegations contained in Paragraph 226 of the Complaint.

227. To the extent that Paragraph 227 refers to the state of mind of Plaintiff and others, Defendants are without knowledge or information sufficient to form a belief as to the truth of the

allegations contained in Paragraph 227 of the Complaint. Defendants otherwise deny the allegations contained in Paragraph 227 of the Complaint.

228. Defendants deny the allegations contained in Paragraph 228 of the Complaint.

229. Defendants deny the allegations contained in Paragraph 229 of the Complaint.

230. Defendants deny the allegations contained in Paragraph 230 of the Complaint.

231. Defendants deny the allegations contained in Paragraph 231 of the Complaint.

PRAYER FOR RELIEF

Defendants admit that Plaintiff demands judgment, but Defendants deny that they are liable in any way or that Plaintiff is entitled to any damages or relief whatsoever.

AFFIRMATIVE DEFENSES

For further answer to Plaintiff's Complaint, Defendants respectfully aver:

FIRST AFFIRMATIVE DEFENSE

Plaintiff's Complaint, or certain counts, fails to state a claim against Defendants upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

If the injuries and damages alleged by Plaintiff in the Complaint were actually sustained, such damages and injuries resulted from a preexisting and/or unrelated medical condition and/or idiosyncratic reaction and not from any act or omission on behalf of Defendants or a defect in Ortho Evra®.

THIRD AFFIRMATIVE DEFENSE

The injuries and damages alleged by Plaintiff in the Complaint may have been caused, in whole or in part, by the acts or omissions of others for whose conduct Defendants are not responsible.

FOURTH AFFIRMATIVE DEFENSE

The injuries and damages alleged by Plaintiff in the Complaint were caused, brought about or contributed to by her own comparative fault, and any recovery by Plaintiff must therefore be reduced proportionately or altogether barred.

FIFTH AFFIRMATIVE DEFENSE

The injuries and damages alleged by Plaintiff in the Complaint were the result of an independent, intervening, and/or superseding cause. Any alleged action or alleged omission on the part of Defendants was not the proximate cause of such damages and injuries.

SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred or reduced by the doctrine of avoidable consequences.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiff has failed to obtain jurisdiction over Defendants.

EIGHTH AFFIRMATIVE DEFENSE

The United States Food and Drug Administration (“FDA”) approved the labeling for Ortho Evra®, and the marketing and/or distribution of Ortho Evra® conformed with FDA requirements and all other applicable statutes at all times pertinent to the Complaint.

NINTH AFFIRMATIVE DEFENSE

Because the FDA approved Ortho Evra®, Plaintiff’s claims that Defendants are strictly liable are barred under the Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and/or the Restatement (Third) of Torts: Products Liability §§ 2,4 and 6 and comments thereto.

TENTH AFFIRMATIVE DEFENSE

The injuries and damages alleged by Plaintiff in the Complaint are or may be due to her assumption of the risk of use of Ortho Evra®, if any, thereby barring Plaintiff from recovery.

ELEVENTH AFFIRMATIVE DEFENSE

Adequate and complete warnings and instructions were provided with Ortho Evra®. Ortho Evra® was neither defective nor unreasonably dangerous when used according to label instructions.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiff’s claims for breach of express or implied warranty are barred by Plaintiff’s failure to give notice.

THIRTEENTH AFFIRMATIVE DEFENSE

Any express or implied warranties alleged to have been made by Defendants were disclaimed.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of warranty are barred by the absence of privity of contract between Plaintiff and Defendants.

FIFTEENTH AFFIRMATIVE DEFENSE

Defendants are entitled to the benefit of all defenses and presumptions which may arise because the design, manufacture, inspection, packaging, issuing of warnings and instructions or labeling of Ortho Evra® were in conformity with the generally recognized, reasonably available and reliable state of the art and prevailing standards in the industry at the time the product was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by the Learned Intermediary Doctrine, or the Informed Intermediary Doctrine and/or the principle of Restatement (Second) of Torts § 388.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction, in that the FDA is charged under the law with regulating prescription drugs, including Ortho Evra®, and is specifically charged with determining the content of warnings and labeling for prescription drugs.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims, in whole or in part, are preempted expressly and impliedly by the Supremacy Clause of the Constitution of the United States of America and by applicable federal statutes and regulations thereunder.

NINETEENTH AFFIRMATIVE DEFENSE

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341 (2001).

TWENTIETH AFFIRMATIVE DEFENSE

If Defendants are found liable to Plaintiff for any non-economic loss, as defined in Article 16 of the New York Civil Practice Law and Rules, and such liability equals 50% or less of the total liability of all persons liable, and the aggregate liability of such other persons equals or exceeds 50% of the total liability. Defendants' liability, if any, to Plaintiff for a non-economic loss shall not exceed Defendants' equitable share determined in accordance with the relative culpability of each person causing or contributing to the total liability for such non-economic loss.

TWENTY-FIRST AFFIRMATIVE DEFENSE

The awarding of punitive damages and Plaintiff's claims for punitive damages are unconstitutional under the constitutions of the United States and the State of New York. The awarding of punitive damages would be unconstitutional because punitive damages are a punishment, a quasi-criminal sanction for which Defendants have not been afforded the specific procedural safeguards prescribed in the New York Constitution as well as the Fifth and Sixth

Amendments to the United States Constitution, and would violate constitutional proscriptions against excessive fines.

TWENTY-SECOND AFFIRMATIVE DEFENSE

With respect to Plaintiff's demand for punitive damages, Defendants specifically incorporate by reference all standards of limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of BMW of North America v. Gore, 517 U.S. 559 (1996); Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001); State Farm Mutual Auto Ins. Co. v. Campbell, 538 U.S. 408 (2003); and Philip Morris USA v. Williams, 549 U.S. ___, 127 S. Ct. 1057 (2007), together with all such standards applicable under New York law.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the First Amendment of the Constitution of the United States and Article I, Section 8 of the Constitution of the State of New York.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Any recovery by Plaintiff must be reduced or offset by amounts Plaintiff has received or will receive from others for the same injuries and damages alleged by Plaintiff in the Complaint pursuant to Section 15-108 of the General Obligation Law.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's causes of action are barred in whole or in part by the applicable statutes of limitations or repose, or by operation of laches.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's causes of action are barred in whole or in part by the doctrines of waiver and equitable estoppel.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Any damages allegedly recoverable by Plaintiff should be reduced in accordance with Rule 4545 of the New York Civil Practice Law and Rules.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred because Defendants did not owe any legal duty to Plaintiff or, if Defendants did owe such a legal duty, Defendants did not breach that duty.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by her abuse and/or misuse of the Ortho Evra® product.

THIRTIETH AFFIRMATIVE DEFENSE

Plaintiff has failed to plead fraud and/or misrepresentation with the particularity requirements under Rule 9(b) of the Federal Rules of Civil Procedure.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff cannot recover under their consumer protection claims because Defendants were not engaged in consumer oriented conduct as required by the New York consumer protection laws.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's consumer protection claims are preempted by New York law, including N.Y. Gen. Bus. Law § 399.

THIRTY-THIRD AFFIRMATIVE DEFENSE

Defendants specifically deny each and every allegation contained in the Complaint by which liability is sought to be imposed upon them, and give notice that they intend to rely upon such other defenses as may become available or appear during discovery in this case and hereby reserve the right to amend this Answer to assert any such defenses.

WHEREFORE, having fully answered, Defendants request that Plaintiff's Complaint against them be dismissed at Plaintiff's cost and that this Court grant any further relief which it deems just and equitable.

JURY DEMAND

Defendants hereby demand a trial by jury of all the facts and issues so triable pursuant to 38(b) of the Federal Rules of Civil Procedure.

Respectfully submitted,

Dated: June 1, 2007

/s/ James. S. Buino

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